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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/911,824 08/15/97 HACKETT, JR.

J 6165.US.01

HM12/0804

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EXAMINER

NELSON, B

ART UNIT

PAPER NUMBER

1648

DATE MAILED:

08/04/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

08/911,824

Applicant(s)

Hackett, et al.

Examiner

Brett Nelson

Group Art Unit

1648



☒ Responsive to communication(s) filed on Jun. 22, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-77 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☐ Claim(s) \_\_\_\_\_ is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 1-77 are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## **DETAILED ACTION**

### **Election/Restriction**

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1, and 2, drawn to an HIV group O env polypeptide, classified in class 530, subclass 350.
  - II. Claims 4-18, drawn to antigen constructs comprising an HIV 1 group O env polypeptide fused to another HIV 1 group O env polypeptide, classified in class 530, subclass 395.
  - III. Claims 19-38, drawn to antigen constructs comprising an HIV 1 group O env polypeptide fused to an HIV 1 group M env polypeptide, classified in class 530, subclass 395.
  - IV. Claims 39-58, drawn to antigen constructs comprising a first HIV 1 env polypeptide, a second HIV 1 polypeptide and at least one additional polypeptide, classified in class 530, subclass 395.
  - V. Claims 59-62, drawn to antigen constructs comprising an HIV 2 env polypeptide fused to a second HIV 2 env polypeptide, classified in class 530, subclass 395.
  - VI. Claims 3, 63-68, drawn to polynucleotides, host cells and expression vectors, classified in classes 536 and 435, subclasses 23.1 and 252.3.

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VII. Claims 69-77, drawn to method of detection and kit, classified in class 435, subclasses 7.1 and 975.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I-V and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used (i.e. polypeptides) in immunochromatographic assays.

Groups I and II recite two different products which have different structures and functions are unobvious and therefore patentably distinct each over the other.

3. Inventions I-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions recite different products which have different biological activities and chemical structures and are patentably distinct each over the other.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, divergent subject matter, the searches are not coextensive and would constitute a serious burden on the examiner to examiner all groups, restriction for examination purposes as indicated is proper.

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5. This application contains claims directed to the following patentably distinct species of the claimed invention:

If Group II is elected, then elect a specie from amongst claims 4-18

If Group III is elected, then elect a specie from amongst claims 19-38

If Group IV is elected, then elect a specie from amongst claims 39-58

If Group V is elected, then elect a specie from amongst claims 59-62.

If Group VI is elected then elect a specie from amongst claims 4, 18, 19, 38, 39, 58, 59 or

62.

If Group VII is elected, then elect a specie from amongst claims 4, 18, 19, 38, 39, 58, 59 or 62. The species recite different antigenic constructs which have different amino acid sequences and are therefore unobvious and patentably distinct each over the other.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (as indicated above) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations

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of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

7. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Brett Nelson, Art Unit 1648 and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Art Unit 1648 FAX telephone number is (703)308-4426. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Brett Nelson whose telephone number is (703) 306-3219.

If the examiner can not be reached, inquiries can be directed to Supervisory Patent Examiner James Housel whose telephone number is (703) 308-4027.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read 'NELSON/bn', with a stylized flourish at the end.

NELSON/bn

August 3, 2000